

the sample for assay as follows: Place a representative number of capsules in a high-speed glass blender with sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(2) *Moisture*. Proceed as directed in § 436.201 of this chapter.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59861, Nov. 22, 1977; 50 FR 19919, May 13, 1985]

**§ 440.141 Nafcillin sodium monohydrate oral dosage forms.**

**§ 440.141a Nafcillin sodium monohydrate tablets.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Nafcillin sodium monohydrate tablets are composed of nafcillin sodium monohydrate with one or more suitable buffers, binders, disintegrants, diluents, and lubricants. Each tablet contains nafcillin sodium monohydrate equivalent to 500 milligrams of nafcillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of nafcillin that it is represented to contain. Its moisture content is not more than 5 percent. It shall disintegrate within 20 minutes. The nafcillin sodium monohydrate used conforms to the standards prescribed by § 440.41(a)(1).

(2) *Labeling*. In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled “nafcillin sodium tablets”.

(3) *Requests for certification; samples*. In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The nafcillin sodium monohydrate used in making the batch for potency, moisture, pH, crystallinity, nafcillin content, and identity.

(b) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(a) The nafcillin sodium monohydrate used in making the

batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay—(1) Potency—(i) Sample preparation*. Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures*. Assay for potency by any of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(a) *Microbiological agar diffusion assay*. Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 2.0 micrograms of nafcillin per milliliter (estimated).

(b) *Iodometric assay*. Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(c) *Hydroxylamine colorimetric assay*. Proceed as directed in § 436.205 of this chapter.

(2) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(3) *Disintegration time*. Proceed as directed in § 436.212 of this chapter, using the method described in paragraph (e)(1) of that section, except use distilled water in lieu of simulated gastric fluid as the immersion fluid.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59862, Nov. 22, 1977; 50 FR 19919, May 13, 1985]

**§ 440.141b Nafcillin sodium monohydrate capsules.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Nafcillin sodium monohydrate capsules are composed of nafcillin sodium monohydrate and one or more suitable and harmless buffer substances and lubricants. Each capsule contains nafcillin sodium monohydrate equivalent to 250 milligrams of nafcillin. The potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of nafcillin

that it is represented to contain. The moisture content is not more than 5.0 percent. The nafcillin sodium monohydrate conforms to the standards prescribed by § 440.41(a)(1).

(2) *Labeling.* In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled "nafcillin sodium capsules".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The nafcillin sodium monohydrate used in making the batch for potency, moisture, pH, crystallinity, nafcillin content, and identity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The nafcillin sodium monohydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 2.0 micrograms of nafcillin per milliliter (estimated) for the microbiological agar diffusion assay and to the prescribed concentration for the iodometric assay.

(ii) *Assay procedures.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter.

(b) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59862, Nov. 22, 1977; 50 FR 19919, May 13, 1985]

**§ 440.141c Nafcillin sodium monohydrate for oral solution.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nafcillin sodium monohydrate for oral solution is a packaged combination of one immediate container of nafcillin sodium monohydrate and one immediate container of an aqueous diluent containing one or more suitable and harmless colorings, flavoring, buffers, dispersants, diluents, and preservatives. When reconstituted as directed in the labeling, each milliliter contains the equivalent of 50 milligrams of nafcillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of nafcillin that it is represented to contain. Its moisture content is not more than 5 percent. When reconstituted as directed in the labeling, its pH is not less than 5.5 and not more than 7.5. The nafcillin sodium monohydrate used conforms to the standards prescribed by § 440.41(a)(1).

(2) *Labeling.* In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled "nafcillin sodium for oral solution".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The nafcillin sodium monohydrate used in making the batch for potency, moisture, pH, crystallinity, nafcillin content, and identity.

(b) The batch for potency, moisture, and pH.

(ii) Samples required:

(a) The nafcillin sodium monohydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Reconstitute as directed in the labeling. Place an accurately measured representative aliquot of the sample into a 250-milliliter volumetric flask and dilute to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1). Mix well. Further dilute an aliquot with solution 1 to the reference concentration